REMARKS

Claims 40-44 and 47-55 are pending. Claims 47-55 stand rejected under 35 U.S.C. § 112, first paragraph as lacking written description. Claim 40 stands rejected under 35 U.S.C. § 102 as being anticipated by Sharan *et al.*, Embryonic Lethality and Radiation Hypersensitivity Mediated by Rad51 in Mice Lacking Brca2, Nature 386:804-810 (04/24/97) ("Sharan *et al.*"), by Sturzbecher *et al.* p53 Is Linked Directly to Homologous Recombination Processes Via Rad 51/RecA Protein InteractionEMBO J. 15:1992-2002 (1996) ("Sturzbecher *et al.*"), and by Scully *et al.* Association of BRCA1 with Rad 51 in Mitotic and Meiotic Cells, Cell, 88:265-275 (01/24/1997) ("Scully *et al.*"); Claims 41, 42 and 43 stand rejected under 35 U.S.C. § 102 as being anticipated by Sturzbecher *et al.*, Scully *et al.*, and Sharan *et al.*, respectively; and Claims 40 and 44 stand rejected under 35 U.S.C. § 103(a) as being obvious over Sturzbecher *et al.* in view of Scully *et al.* and in further view of Sharan *et al.*

Claim 40 has been amended to recite with greater clarity and particularity certain features of Applicants' invention. Support for the amendment can be found throughout the specification, and more specifically (for example) at 27:20-22, 10:15-23 (defining patient), and 25:16-26:2 (describing pharmaceutical delivery). Thus, no new matter is presented by the amendment and entry thereof is respectfully requested.

Applicants recognize and thank the Examiner for the renumbering of the claims. A copy of the currently pending claims, as renumbered and after entry of the present amendment, are attached hereto for the Examiner's convenience.

The Rejections Under 35 U.S.C. Section 112, First Paragraph

Claims 47-55 stand rejected under 35 U.S.C. § 112, first paragraph as lacking sufficient written description to reasonably convey to one skilled in the relevant art that the Applicants had possession of the claimed invention at the time of filing.

Unlike the "enablement" requirement, the "written description" requirement of 35 U.S.C. §112, first paragraph is not concerned with support commensurate with the breadth of

the claims. The essential purpose of the written description requirement is to show the possession of the claimed invention as of the filing date as a *prima facie* date of invention. *Union Oil Co. of California v. Atlantic Richfield Co.*, 54 USPQ2d 1227, 1232 (Fed. Cir. 2000); *In re Smith*, 178 USPQ 620,623 (CCPA 1973). The written description requirement does not require *ipsis verbis* description of the claimed subject matter in the specification in order to satisfy the description requirement. *Union Oil*, 178 USPQ2d at 1232 (citations omitted); *In re Lukach, Olson, and Spurlin*, 169 U.S.P.Q. 795, 796 (CCPA 1971). Rather, "'the description must clearly allow persons of ordinary skill in the art to recognize that [the applicant] invented what is claimed.'" *Id.* (quoting *In re Gosteli,* 10 USPQ2d 1614, 1618 (Fed. Cir. 1989)).

Claim 47, and Claims 48-55 depending therefrom, require *inter alia* a human cell with a recombinant nucleic acid encoding a Rad51 protein and a recombinant nucleic acid encoding a tumor suppressor protein.

The Examiner argues that the written description is limited to the recombinant nucleic acids for the purpose of expressing the same and isolating and purifying the resultant proteins for use in binding assays and to generate antisera. Thus, the Examiner concludes that the specification does not provide sufficient written description for invention of Claim 47 and its dependant Claims 48-55. Applicants respectfully disagree.

The specification outlines that Rad51 may function interactively with a number of tumor suppressor genes, and thus compositions comprising combinations of these genes may be useful in methods of diagnosis and gene therapy treatment. 10:1-23; 17:11-14; 26:22-29. The specification goes on to outline several compositions of Rad51 genes and tumor suppressor genes that can be used in diagnosis and gene therapy treatments. 26:22-29. The specification describes and provides an example of administering a gene encoding Rad51 to a human cell. 17:13-14; 54:22-55:12. The specification also specifically points out that these compositions can be administered to a cell or patient. 27:20-22. The written description is not limited to the isolation and purification of proteins for recombinant nucleic acids, as urged by the Examiner. Rather, the description relied upon by the Examiner describes the

isolation and purification of "recombinant proteins" as one of any number of characteristics that distinguish a recombinant protein from a protein naturally produced by the cell. 27:5-19. Lastly, the specification outlines a number of suitable cells (*see, e.g.,* 11:1-5), and that patients can be human (10:16-24 (providing the definition of patient)).

The specification clearly describes to the skilled artisan that the Applicants invented cells, more particularly human cells comprising a recombinant nucleic acid encoding a Rad51 protein and a recombinant nucleic acid encoding a tumor suppressor protein.

Therefore, the specification fully describes to the skilled artisan that the Applicants were in possession of the claimed subject matter at the time of filing the present application. Accordingly, the rejection of Claims 47-55 under 35 U.S.C. § 112, first paragraph as lacking sufficient written description should be withdrawn.

The Rejections Under 35 U.S.C. § 102

Claim 40 stands rejected under 35 U.S.C. § 102 as being anticipated by each of Sharan *et al.*, Sturzbecher *et al.*, and Scully *et al.*, and Claims 41, 42, and 43 stand rejected under 35 U.S.C. § 102 as being anticipated by Sturzbecher *et al.*, Scully *et al.*, and Sharan *et al.*, respectively.

Claim 40, as amended, recites a pharmaceutical composition comprising a nucleic acid encoding a Rad51 protein, a nucleic acid encoding a tumor suppressor protein, and a pharmaceutical carrier.

An anticipation rejection requires that a single reference expressly or inherently disclose each and every element of a claim. *In re Paulsen*, 31 USPQ2d 1671, 1673 (Fed. Cir. 1994); MPEP § 2131 (citing *Richardson v. Suzuki Motor Co.*, 9 USPQ2d 1913, 1920 (Fed. Cir. 1989).

The Examiner argues, *inter alia*, that each cited reference discloses the recited Rad51 nucleic acid and tumor suppressor nucleic acid in a cell and that the cell is a physiological carrier. Thus, the Examiner concludes that each and every element of Claim 40 is taught by each of the three references. Applicants respectfully disagree.

Applicants have amended Claim 40 to recite, *inter alia*, a pharmaceutical carrier. Applicants submit that a cell is not a pharmaceutical carrier, as that term is understood within the art. For this reason alone, and without admitting to the propriety of the Examiner's other assertions regarding the teachings of the three references, Claim 40 is not anticipated by any of the three cited references.

Claims 41-43 depend from Claim 40, and therefore contain each and every limitation of this claim. As a consequence, none of the three cited references anticipate these claims for the same reason the references do not anticipate the parent claim.

Accordingly, Applicants respectfully request that the rejection of Claims 40-43 under 35 U.S.C. § 102 be withdrawn.

The Rejections Under 35 U.S.C. § 103(a)

Claims 40 and 44 stand rejected under 35 U.S.C. § 103(a) as being obvious over Sturzbecher *et al.* in view of Scully *et al.*, in further view of Sharan *et al.*

When rejecting claims under 35 U.S.C. § 103, the Examiner bears the burden of establishing a *prima facie* case of obviousness. *See, e.g.*, *In re Bell*, 26 USPQ2d 1529 (Fed. Cir. 1993); M.P.E.P. § 2142. To establish a *prima facie* case, three basic criteria must be met: (1) the prior art must provide one of ordinary skill with a suggestion or motivation to modify or combine the teachings of the references relied upon by the Examiner to arrive at the claimed invention; (2) the prior art must provide one of ordinary skill with a reasonable expectation of success; and (3) the prior art, either alone or in combination, must teach or suggest each and every limitation of the rejected claims. The teaching or suggestion to make the claimed invention, as well as the reasonable expectation of success, must come from the prior art, not Applicant's disclosure. *In re Vaeck*, 20 USPQ2d 1438 (Fed. Cir. 1991); M.P.E.P. § 706.02(j). If any one of these criteria is not met, *prima facie* obviousness is not established.

Claim 40, as amended, recites a pharmaceutical composition comprising a nucleic acid encoding a Rad51 protein, a nucleic acid encoding a tumor suppressor protein, and a

pharmaceutical carrier.

The Examiner argues, *inter alia*, that each cited reference discloses the recited Rad51 nucleic acid and tumor suppressor nucleic acid in a cell and that the cell is a physiological carrier. The Examiner argues that none of the three references taken alone teach the combination of the genes recited in Claim 44, but that the combination is obvious in view of the three references taken together. Thus, the Examiner concludes that Claims 40 and 44 are obvious in light of the three references. Applicants respectfully disagree.

Applicants have amended Claim 40 to recite, *inter alia*, a pharmaceutical carrier. Applicants submit that a cell is not a pharmaceutical carrier, as that term is understood within the art. Applicants further submit that the teachings of the references, taken alone or in combination, do not teach or suggest a composition comprising, *inter alia*, a pharmaceutical carrier as required by Claim 40. Therefore, the three cited references, taken alone or in combination, fail to teach each and every element of the claimed invention. For this reason alone, and without admitting to the propriety of the Examiner's other assertions regarding the teaching of the three references, the Examiner has failed to establish a *prima facie* case of obviousness against Claim 40.

Claim 44 depend from Claim 40, and therefore contains each and every limitation of this claim. As a consequence, the Examiner has failed to establish a *prima facie* case of obviousness against Claim 44 for the same reasons he failed to do so for Claim 40.

Accordingly, Applicants respectfully request that the rejection of Claims 40 and 44 under 35 U.S.C. § 103 be withdrawn.

CONCLUSION

Applicants respectfully submit that the claims are now in condition for allowance and an early notification of such is solicited. If, upon review, the Examiner feels there are additional outstanding issues, the Examiner is invited to call the undersigned attorney.

Respectfully submitted,

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Appendix of Pending Claims

40. (Twice Amended) A pharmaceutical composition comprising:
a) nucleic acid encoding a Rad51 protein;
b) nucleic acid encoding a tumor suppressor protein; and
c) a pharmaceutical carrier.

41. (Amended) A composition according to claim 40 wherein said tumor suppressor protein is p53.

42. (Amended) A composition according to claim 40 wherein said tumor suppressor protein is BRCA1.

43. (Amended) A composition according to claim 40 wherein said tumor suppressor protein is BRCA2.

44. (Amended) A composition according to claim 40 comprising:
a) nucleic acid encoding a Rad51 protein;
b) nucleic acid encoding a BRCA1 protein;
c) nucleic acid encoding a BRCA2 protein; and
d) nucleic acid encoding a p53 protein.

47. A human cell comprising a recombinant nucleic acid encoding a RAD51 protein and a recombinant nucleic acid encoding a tumor suppressor protein.

48. A human cell according to claim 47 wherein said tumor suppressor protein is BRCA1.

49. A human cell according to claim 47 wherein said tumor suppressor protein is BRCA2.

50. A human cell according to claim 47 comprising:
a) a recombinant nucleic acid encoding a RAD51 protein;
b) a recombinant nucleic acid encoding a BRCA1 protein;
c) a recombinant nucleic acid encoding a BRCA2 protein; and
d)a recombinant nucleic acid encoding a p53 protein.

51. A human cell according to claim 47 wherein said human cell is a breast tissue cell.

52. A human cell according to claim 47 wherein said human cell is a cancerous breast tissue cell.

53. A human cell according to claim 47 wherein said human cell is a cancerous cell.

54. A human cell according claim 47 wherein said human cell is in a cell culture.

55. A human cell according claim 47 wherein said human cell is isolated.